

SENATE BILL 1617
By Harper

AN ACT to create the Tennessee Birth Defects Registry and to amend Tennessee Code Annotated, Title 4; Title 33 and Title 68, Chapter 1.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part to be appropriately designated:

Section 68-1-___1. Creation of Birth Defects Registry.

(a) The commissioner of health shall establish in the department a program to:

- (1) Identify and investigate birth defects; and
- (2) Maintain a central registry of cases of birth defects.

(b) The department shall design the registry program to:

- (1) Provide information to identify risk factors and causes of birth defects;
- (2) Provide information on other possible causes of birth defects;
- (3) Provide for the development of strategies to prevent birth defects;
- (4) Provide for interview studies about the causes of birth defects; and
- (5) Provide for the collection of birth defect information.

Section 68-1-___2.

(a) The department shall adopt rules, regulations and procedures to govern the operation of the registry program and to carry out the intent of this section. All such rules, regulations and procedures shall be promulgated in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

(b) The department in its rules and regulations shall specify the types of information to be provided to the birth defects registry and the persons and entities who are required to provide such information to the birth defects registry.

(c) The department by rule shall prescribe the manner in which records and other information are made available.

Section 68-1-___3.

The following persons who act in compliance with this section are not civilly or criminally liable for furnishing the information required under this section:

(a) A hospital, clinical laboratory, genetic treatment center or other health care facility;

(b) An administrator, officer or employee of a hospital, clinical laboratory, genetic treatment center or other health care facility; and

(c) A physician or employee of a physician.

Section 68-1-___4.

Information collected and analyzed by the department under this act shall be placed in a central registry to facilitate research and to maintain security.

(a) Data obtained under this section directly from the medical records of a patient is for the confidential use of the department and the persons or public or private entities that the department determines are necessary to carry out the intent of this section. The data is privileged and may not be divulged or made

public in a manner that discloses the identity of an individual whose medical records have been used for obtaining data under this section.

(b) Information that may identify an individual whose medical records have been used for obtaining data under this section is not available for public inspection under the Tennessee Public Records Act.

(c) Statistical information collected under this section is public information.

Section 68-1-___5.

The department may use the registry to:

(a) Investigate the causes of birth defects and other health conditions as authorized by statute;

(b) Design and evaluate measures to prevent the occurrence of birth defects, and other conditions; and

(c) Conduct other investigations and activities necessary for the board and the department to fulfill their obligation to protect the public health.

Section 68-1-___6.

Any person or entity that misuses the information provided to the registry shall be subject to a civil penalty of five hundred dollars (\$500) for each such failure or misuse. Such penalty shall be assessed and levied by the board after a hearing, and all such penalties collected shall be deposited into the general fund.

Section 68-1-___7.

The commissioner of health may appoint or delegate such commissioner's authority for the purposes of this section to an advisory committee, not to exceed ten (10) persons, to assist in the design and implementation of this central registry with representation from relevant groups including, but not limited to, hospitals, physicians, board-certified clinical geneticists, personnel of the department, personnel of other appropriate state agencies, disabled persons (resulting from a birth defect) and parents

of disabled children (resulting from a birth defect). If the commissioner creates a central registry advisory committee, such board shall consult and be advised by the committee on the promulgation of rules, regulations and procedures for the purposes of this section.

SECTION 2. For the purpose of promulgating rules and regulations, this law shall take effect upon becoming a law. For all other purposes, this act shall take effect on July 1, 2003, the public welfare requiring it.